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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/454,740

Applicant(s)

Hillebrand et al.

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 27, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-11, and 27-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-11, and 27-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: Detailed Action

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DETAILED ACTION

Specification

1. Claim 1 has been canceled without prejudice towards further prosecution. New claims 30-36 have been added. Claims 2-5, 7-11, and 27-29 have been amended.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 33 is rejected under the second paragraph of 35 U.S.C. 112. Claim 33 recites the limitation "the column" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 30-36, 2-7, and 27-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Heath (U.S. Patent 5,973,137) (October 26, 1999).

Heath teaches a kit for isolating nucleic acids in the absence of a chaotropic salt, wherein one or more nucleic acids bind to a substrate (Abstract), the kit comprising:

a) a lysis/buffer system comprising at least one antichaotropic salt (Ammonium chloride in this case) at a concentration that allows binding of the one or more of the nucleic acids to the substrate (Column 4, lines 9-19 and Column 3, lines 49-59 and Example 1).

B) the substrate (Example 1, Column 10, lines 65-67, absorbent paper in this case), and

c) optionally, one or more detergents and/or other additives (Column 3, lines 49-59, and 3-14).

Heath teaches a kit, wherein at least one of the protein degrading enzyme is proteinase K (Column 2, lines 1-11).

Heath teaches a kit, comprising a wash buffer having at least about 50% ethanol effective to retain the nucleic acids to the solid substrate during washing (Example 1).

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Heath teaches a kit, wherein the nucleic acids are DNA and RNA (Abstract, Column 2, line 39 to Column 4, line 62).

Heath teaches a kit, wherein the antichaotropic component is a salt chosen from ammonium chloride (Example 1).

Heath teaches a kit, wherein the lysis/buffer system contains detergents and/or other additives selected from EDTA, sodium citrate, dodecylsulfate (Column 3, lines 49-59, and 3-14 and Example 1).

Heath teaches a kit, wherein the lysis/buffer system contains an alcohol (Example 1).

Heath teaches a kit, wherein the lysis/buffer system is an aqueous solution (Example 1)

Heath teaches a kit, wherein the complex starting material is chosen from whole blood, plant and animal tissues, microbioplate, and swabs (Abstract).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

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the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 8 is rejected under 35 U.S.C. 103 (a) over Heath (U.S. Patent 5,973,137) (October 26, 1999) in view of Summerton et al. (U.S. Patent 6,060,246) (May 9, 2000).

Heath teaches the kit of claims 30-36, 2-7, and 27-28 as described above.

Heath does not teach the formulations wherein the buffer system is a solid formulation stable in storage in reaction vessel ready for use .

Summerton et al teach the formulations wherein the buffer system is a solid formulation stable in storage in reaction vessel ready for use (Column 10, lines 52-57).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute dried buffer of Summerton et al in the nucleic acid isolation method of Heath, since Summerton et al. state, "This pH adjustment can be readily carried out as part of the specimen preparation step, simply by incorporating in the specimen receiving container a suitable buffer, preferably in dry form, effective to adjust the specimen to the proper pH for electrostatic capture of polynucleotides (Column 10, lines 52-57)". An ordinary practitioner would have been motivated to substitute dried buffer of Summerton et al. in the nucleic acid isolation method of Heath, in order to achieve the express advantage of a system, as noted by

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Summerton et al, which provides effective adjustment of the specimen to the proper pH for electrostatic capture of polynucleotides .

8. Claims 9-11 are rejected under 35 U.S.C. 103 (a) over Heath (U.S. Patent 5,973,137) (October 26, 1999) in view of Woodard et al. (U.S. Patent 5,650,506) (July 12, 1997).

Heath teaches the kit of claims 30-36, 2-7, and 27-28 as described above.

Heath does not teach the glass fiber membranes as substrates and formulations wherein all carriers which have a negatively functionalised surface or functionalised surfaces which may be converted to a negative charge potential serve as solid phase and wherein the surface of the carrier is modified by a hydroxyl group.

Woodard et al teach the glass fiber membranes as substrates and formulations wherein all carriers which have a negatively functionalised surface or functionalised surfaces which may be converted to a negative charge potential serve as solid phase and wherein the surface of the carrier is modified by a hydroxyl group (Abstract and Column 2, lines 40-57 and column 4, lines 44-54).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute the negatively charged surface containing solid phase of Woodard et al. in the nucleic acid isolation method of Heath since Woodard et al. state, "The modified glass fiber membranes of the present invention allows very quick and efficient isolation of DNA from biological samples. They can substantially decrease the time required to process pure DNA from biological samples, compared with currently used techniques, and in some cases

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generate high quantities of pure DNA (Column 4, lines 44-49)". An ordinary practitioner would have been motivated to substitute the negatively charged surface containing solid phase of Woodard et al. in the nucleic acid isolation method of Heath, in order to achieve the express advantage of a system, as noted by Woodard et al, which allows very quick and efficient isolation of DNA from biological samples and in some cases generate high quantities of pure DNA.

9. Claim 29 is rejected under 35 U.S.C. 103(a) over Heath (U.S. Patent 5,973,137) (October 26, 1999) in view of Nochumson et al. (U.S. Patent 5,552,325) (September 3, 1996).

Heath teaches the kit of claims 30-36, 2-7, and 27-28 as described above.

Heath does not teach the elution buffer comprising Tris-HCl, TE, and water.

Nochumson et al teach the elution buffer comprising Tris-Hcl, TE, and water (Column 12, lines 34-58).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the wash and elution buffer of Nochumson et al. in the nucleic acid isolating system of Heath since Nochumson et al. state, "It is important to maintain a high enough ionic strength to avoid washing off bound DNA (Column 12, lines 39-41)". An ordinary practitioner would have been motivated to combine and substitute the wash and elution buffer of Nochumson et al. in the nucleic acid isolating system of Heath in order to achieve the express advantage of a buffer system, as noted by Nochumson et al, which avoid washing off bound DNA by the wash buffer and enhances elution at a low ionic strength.

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Response to Amendment

10. In response to amendment, all previous 103(a) rejections have been withdrawn. However, new 112 (second paragraph), 102(e) and 103(a) rejections have been included.

Response to Arguments

11. Applicant's arguments and 132 declaration with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's 132 declaration with respect to all pending claims have been considered but is not persuasive. The declaration under 37 CFR 1.132 filed on December 27, 2002 is insufficient to overcome the rejection of all pending claims based upon 103(a) rejections as set forth in the last Office action because: The declaration does not provide guidance commensurate in scope with the claim. For example, the declaration discloses only two antichaotropic salt ammonium chloride at four different concentrations (0.1 M, 1M, 1.5M, and 2.0M), whereas the claims broadly encompasses any antichaotropic salt at any concentrations.

In response to applicant's argument that antichaotropic salts affirmatively promote the binding of DNA to a support, rather than the binding simply resulting from the absence of the chaotropic salt, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use

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must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

March 3, 2003


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